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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,284	07/22/2004	Fabio Rinaldi	27419/150	1852

7590 03/02/2006

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EXAMINER

HARLE, JENNIFER I

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/502,284

Applicant(s)

RINALDI ET AL.

Examiner

Jennifer I. Harle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 9-12 is/are rejected.
- 7) ☐ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-12 are pending and are subject to an Election/Restriction Requirement. Claims 5-8 are withdrawn. Claims 1-4 and 9-12 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I in the reply filed on October 31, 2005 is acknowledged. The traversal is on the ground(s) that there is no undue burden because the International Tribunal searched the entire set of claims. This is not found persuasive because the method encompasses pathologies and word searches that are different from a mere pharmaceutical/dietetic containing spermidine alone, which would be broader and more cumbersome.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 5-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 28, 2005.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Fahl, et al., US 2003/0118539 A1.

Fahl discloses the use of polyamine effectors, specifically spermidine, administered locally as a pharmaceutical preparation, i.e. formulated as a cream, lotion, ointment or gel, to reduce or prevent alopecia. Abstract, [0007], [0008][0023], [0024], [0025], [0026], [0028], [0032], [0042], [0043], [0064], [0065], [0114], [0115], [0116], [0117], [0119], [0141], [0142], [0143], [0145], [0149], [0173], Table 1.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 4, and 12 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fahl, et al., US 2003/0118539 A1.

Fahl discloses the use of polyamine effectors, specifically spermidine, administered locally as a pharmaceutical preparation, i.e. formulated as a cream, lotion, ointment or gel, to reduce or prevent alopecia. Abstract, [0007], [0008][0023], [0024], [0025], [0026], [0028], [0032], [0042], [0043], [0064], [0065], [0114], [0115], [0116], [0117], [0119], [0141], [0142], [0143], [0145], [0149], [0173], Table 1. While not explicitly taught, Fahl implicitly discloses that the hair is made more robust following administration because it withstands chemotherapy and is not lost while undergoing said treatment. Moreover, Fahl discloses that an especially

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insidious side effect from chemotherapy and/or radiation is alopecia and that alopecia or hair loss is the most common hair growth disorder in humans and is often the cause of great concern in affected individuals ranking above vomiting as an important concern in chemotherapy. [0008] Additionally, a NCI study has indicated that hair loss during chemotherapy is the most psychologically debilitating aspect of cancer treatment, estimating that approximately 60-70% of all patients receiving cancer chemotherapy experience alopecia and may lead to a refusal of further chemotherapy. [0008]. Fahl further teaches that this invention relates to topical delivery of polyamine effectors to locally protect the normal epithelial cells in the skin and hair follicles during cancer chemotherapy and that the polyamine effector-containing pharmaceutical preparation described above, where the administration of the polyamine effector reduces or eliminates the toxic side effects of cancer therapy, polyamine effectors protect those cells from the damaging side-effects of chemotherapy, such as alopecia. [0008], [0024], [0025], [0026], [0032], [0042]. Thus, it would have been obvious to one of ordinary skill in the art that administering the spermidine topically as a lotion would have made the hair more robust, as spermidine reduces or prevents the loss of the hair under the extreme conditions of chemotherapy following administration.

8. Claims 1, 4, 9-11 are rejected under 35 U.S.C. 102(b) as anticipated by as obvious over Dietary supplements market in Italy: Anti-ageing products, OTC News & Market Report, Dec 1993 with evidence provided by Rinaldi, et al., Biogenin-based dietary additives. Stimulation of hair shaft growth, Cosmetic Technology, 2002, 5(6), 9-15 (Abstract only)(cited for purposes of ingredients and comparison of ownership of Bioscalin only).

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OTC discloses an oral formulation of Giuliani's Bioscalin for anti-aging. According to Rinaldi, et al. in Cosmetic Technology Giuliani's Bioscalin contains methionine, vitamin C, polypheonls, vitamin E, calium pantothenate, Zinc (as amino acid chelate), vitamin B6, copper (as amino acid chelate, folic acid and biotin. Without evidence to the contrary, it is presumed that the products are the same as the come from the same manufacturer and carry the same brand name. As Giuliani's Bioscalin contains spermidine as an active principle it is implicit that is would act in the same manner as the claimed methods.

Allowable Subject Matter

9. Claims 2-3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

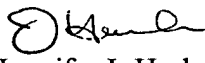
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jennifer I. Harle
Examiner
Art Unit 1654

February 27, 2006